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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,602	09/21/2005	Nahum Sonenberg	GOUD:057US	5675

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EXAMINER	
HORNING, MICHELLE S	
ART UNIT	PAPER NUMBER
1648	

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12/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,602	SONENBERG ET AL.	
	Examiner	Art Unit	
	Michelle Horning	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-13* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-3, drawn to a culture system for HCV comprising HCV-infected and non-infected cells.

Group 2, claim(s) 4, drawn to a culture system for HCV which enables drug screening and development.

Group 3, claim(s) 5, drawn to method of generating a vaccine.

Group 4, claim(s) 6, drawn to a method of activating HCV replication.

Group 5, claim(s) 7-8, drawn to a co-culturing system for HCV replication.

Group 6, claim(s) 9, drawn to a screening assay.

Group 7, claim(s) 10-11, drawn to a method of identifying an anti-HCV activity.

Group 8, claim(s) 12-13, drawn to a compound having a therapeutic effect on HCV.

The inventions listed as Groups 1-8 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The shared technical features, if present, are disclosed by the prior art.

The shared technical feature of Groups 1, 4 and 5 is a method of culturing cells or a cell culture system for the replication of HCV. Shimizu and Yoshikura (1994) disclose such a

method and composition. More specifically, this reference discloses a method for culturing cells or a cell culture which supports the genome replication of HCV (see Abstract). Further, a human lymphocytic cell line, HPBMa, is used in the cell culture. Cytokines, including IFN-alpha, are added to the system. Lastly, they teach that the disclosed system will be useful for further screening of anti-HCV substances and analysis of modes of action (see page 8408).

Group 2 has no special technical feature because the claim does not specify what products or method steps comprise the "system". Of note, it is not clear whether the system refers to a composition or a method.

The special technical feature of Group 3 is a method of generating a HCV vaccine comprising pulsing of DCs, co-cultured with lymphocytes from a HCV-seropositive individual. Kanto et al (1999) disclose the allostimulatory capacity of DCs from HCV-infected individuals. They showed that core-pulsed HCV-DC retained the potential for autologous T cell proliferation (see Abstract). The authors found that DC from HCV-infected individuals exhibited an impaired stimulatory potential against allogeneic CD4 T cells and exogenous IL-2 or IL-12 restored such defective DC capacity, which offers promise for the modulation of DC functions (see page 5585).

The special technical feature of Groups 6 and 7 is a screening assay for testing an agent with anti-HCV activity. These Groups differ in their special technical feature because they do not require a co-culture or a mitogen.

Group 8 has no special technical feature because it is drawn to a compound that has yet to be identified.

Election of Species

If Group 1 or 8 is elected, a further election of species is required.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Activating compositions (Group 1): a. phytohaemagglutinin and IL-2; b. Staphyloccoccus aureas crown 1 and IL-4; and c. SAC, IL-2 and IL-4.

Compound having a therapeutic effect on HCV (Group 8).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1-3 and 12-13.

The following claim(s) are generic: claims 1-3 with respect to the activating composition and claims 12 and 13 with respect to the compound.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species do not have a common structure, such that, a significant structural element is shared by all of the alternatives.

Conclusions

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michelle Horning
Patent Examiner

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